IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF MISSOURI SOUTHWESTERN DIVISION

TERESSA HAGERMAN,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. 3:20-05108-CV-RK
	)	
PFIZER, INC., PFIZER PATIENT ASSISTANCE FOUNDATION, INC.,	)	
	)	
	)	
Defendants.	)	

ORDER ON DEFENDANTS' MOTION TO DISMISS

Before the Court is Defendants Pfizer, Inc. and Pfizer Patient Assistance Foundation, Inc's (collectively "Defendants") motion to dismiss for failure to state a claim. (Doc. 14.) The motion is fully briefed. (Docs. 15, 27, 36.) After careful consideration, the motion is **DENIED**. Also before the Court, are Plaintiff's motion for leave to file a sur-reply (Doc. 38) and Defendants' motion to stay discovery. (Doc. 41.) Those motions are **DENIED as MOOT**.

Background[1]

In May 2017, Plaintiff was bitten by a dog on her right middle finger. Plaintiff sought treatment for an infection that developed in the wound. Judy K. Parton, M.D. and Carla Reed, N.P. undertook to provide medical care and treatment to Plaintiff at offices in Nevada, Missouri. On or about July 5, 2017, Dr. Parton concluded the Plaintiff probably had osteomyelitis in the bone of her right third distal finger, and recommended that, depending upon the results of a bone scan, that Linezolid, also known as Zyvox, was appropriate.

Zyvox is an oxazolidinone-class antibacterial drug that is indicated for treatment of the following infections caused by susceptible Gram-positive bacteria: nosocomial pneumonia; community acquired pneumonia; complicated skin and skin structure infections, including diabetic foot infections, without concomitant osteomyelitis; uncomplicated skin and skin structure infections; and vancomycin-resistant enterococcus faecium infections. Peripheral neuropathy is a known complication in patients treated with Zyvox, primarily in patients treated for more than twenty-eight days.

[1] Unless otherwise noted, all facts are taken from the Complaint (Doc. 1) and are accepted as true for the present motion.

Dr. Parton directed N.P. Reed to contact a patient assistant program ("RSVP"), run by Defendants Pfizer, Inc., ("Pfizer") and Pfizer Patient Assistance Foundation, Inc., ("PPAF") to inquire if the medication could be obtained through patient assistance, due to Plaintiff being uninsured. N.P. Reed contacted Defendants and the RSVP program to obtain Zyvox for Plaintiff. N.P. Reed filled out an application to the Pfizer RSVP program on an enrollment form that indicated that Zyvox was being requested, and provided information about the Plaintiff. However, the enrollment form did not seek any information about the details of the diagnosis, nor did it identify the physician who was treating the Plaintiff.

N.P. Reed was able to obtain one presumptive supply of Zyvox, which was provided to Plaintiff due to the actions of Defendants, and which was taken by Plaintiff.[2] By early August 2017, Plaintiff's supply of Zyvox began to run low, and she had already been on Zyvox for approximately twenty-eight days. On August 7, 2017, N.P. Reed again made inquiry to the Defendants and the Pfizer RSVP program, requesting additional Zyvox for extended usage and dosage beyond 28 days. On August 7, 2017, Pontina Dorsey, a representative of the Pfizer RSVP Program located in Charlotte, North Carolina, wrote to N.P. Reed, noting that Plaintiff had been eligible for one presumptive supply of Zyvox, but that if Plaintiff was to continue in the patient assistance program and obtain additional Zyvox, a new enrollment form would have to be filled out and submitted. Nurse Reed then filled out a form titled, Enrollment Form: Patient Application, which was then signed by Plaintiff and sent to the Pfizer RSVP program. The enrollment form indicated Zyvox was being requested and provided information about the Plaintiff. However, the enrollment form did not seek any information about the details of the diagnosis, nor did it identify the physician who was treating Plaintiff.

In addition, a new enrollment form, titled Patient Application and Enrollment Form: Healthcare Provider Application, was submitted by Nurse Reed on August 7, 2017. On the healthcare provider application, Nurse Reed provided an ICD-9 code; specified the disease being treated as osteomyelitis of the right middle finger; included information about the Plaintiff such as name, date of birth, and drug allergies of the Plaintiff; and requested four refills at the full dosage amount.

[2] It is unclear from the Complaint which entity provided the Zyvox to Plaintiff and on which date she began taking it.

On August 8, 2017, Pontina Dorsey of the Pfizer RSVP Program informed Nurse Reed that Plaintiff's application had been approved and Plaintiff was eligible to receive up to a twelve-month supply of Zyvox through the RSVP Program. The letter indicated that Plaintiff would receive an electronic benefit card identification number for her Zyvox. The letter also provided: "We will monitor card activity and will contact you and/or your patient with any concerns." Pursuant to this approval, Plaintiff continued to receive Zyvox from her local pharmacy directly through the auspices of the Pfizer RSVP Program. Plaintiff continued to take Zyvox for an extended period of time greatly in excess of twenty-eight days.

After an extended period of taking Zyvox, Plaintiff developed symptoms of peripheral neuropathy, bilateral lower extremity numbness, and right shoulder pain, which grew worse over time. After a steady and extended course of Zyvox of at least ninety days, Plaintiff stopped taking Zyvox on October 13, 2017. By the time Plaintiff stopped taking Zyvox, the peripheral neuropathy she suffered secondary to the Zyvox overdose was permanent and resulted in debilitating injuries.

Plaintiff alleges that prior to the actions of Defendants in approving Plaintiff for a supply of Zyvox, Defendants took no action to ensure that N.P. Reed was qualified medically or licensed properly to prescribe Zyvox for any period or for a period in excess of twenty-eight days. Defendants took no action to make certain that Zyvox prescribed in excess of twenty-eight days was medically appropriate for Plaintiff and not contraindicated.

Plaintiff alleges she would not have taken the Zyvox through October 12, 2017 had Defendants told her Zyvox was unsafe and harmful when consumed for this extended period for treatment of her known condition.

Legal Standard

Under Rule 12(b)(6) of the Federal Rules of Civil Procedure, a claim may be dismissed for "failure to state a claim upon which relief can be granted." A complaint must provide "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). Generally, the Court "accept[s] the allegations contained in the complaint as true and draw[s] all reasonable inferences in favor of the nonmoving party." *Cole v. Homier Dist. Co.*, 599 F.3d 856, 861 (8th Cir. 2010) (quoting *Coons v. Mineta*, 410 F.3d 1036, 1039 (8th Cir. 2005)). The principle that a court must accept as true all of the allegations contained in a complaint does not apply to legal conclusions, however. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

To determine whether a complaint states a claim, the Court looks at two factors. First, the

Court must identify the allegations that are "not entitled to the assumption of truth." *Iqbal*, 556 U.S. at 678. In other words, to state a claim, a complaint must plead more than "legal conclusions" and "[t]hreadbare recitals of the elements of a cause of action [that are] supported by mere conclusory statements." *Id.* at 678. Second, the Court must determine whether the complaint states a plausible claim for relief, which is more than a "mere possibility of misconduct." *Id.* at 679. This step is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id.* The Court must review the factual allegations "to determine if they plausibly suggest an entitlement to relief." *Id.* When faced with alternative explanations for the alleged misconduct, the Court may exercise its judgment in determining whether Plaintiff's conclusion is the most plausible or whether it is more likely that no misconduct occurred. *Id*. at 681-82.

Discussion

Defendants move to dismiss the Complaint for failure to state a claim. The Court will address each of Defendants' arguments in turn.

I. Plaintiff's Strict Liability- Failure to Warn Claim

Pursuant to Missouri law, the elements of strict liability-failure to warn are: (1) the defendant sold the product in question in the course of its business; (2) the product was unreasonably dangerous at the time of sale when used as reasonably anticipated without knowledge of its characteristics; (3) the defendant did not give adequate warning of the danger; (4) the product was used in a reasonably anticipated manner; and (5) the plaintiff was damaged as a direct result of the product being sold without an adequate warning. *Tune v. Synergy Gas Corp.*, 883 S.W.2d 10, 13 (Mo. 1994) (en banc); *see also* Mo. Rev. Stat. § 537.760. To establish causation, a plaintiff also must show: (1) that the product for which there was no warning must have caused plaintiff's injuries, and (2) that a warning would have altered the behavior of those involved in the accident. *Arnold v. Ingersoll-Rand Co.*, 834 S.W.2d 192, 194 (Mo. 1992) (en banc).

Defendants first argue PPAF cannot be liable for strict liability because it neither manufactured, sold, or distributed Zyvox and that PPAF is a charitable organization. As to whether PPAF manufactured, sold, or distributed Zyvox, Plaintiff specifically pleads that PPAF sold and/or distributed Zyvox. (Doc. 1, ¶ 32.) Accepting that allegation as true, Defendants' argument fails. Defendants also cite to *Katz v. Slade*, 460 S.W.2d 608, 613 (Mo. 1970) for the proposition that a charitable organization cannot be held strictly liable because it lacks a profit motive. However,

Katz does not hold a charitable organization can never be found strictly liable for failure to warn.[3] *Id.* Rather, the court in *Katz* looked at the product in question, the use of the that product, and the actions taken by the defendant in the promotion and warnings regarding the product. *Id.* Such questions are better reserved for summary judgment after a factual record has been established.

Second, Defendants argue Plaintiff insufficiently alleges a failure to warn of the risk of neuropathy with prolonged use of Zyvox. "Generally, the adequacy of a warning is a fact question for the jury." *Barron v. Abbott Lab'ys, Inc.*, 529 S.W.3d 795, 799 (Mo. 2017) (applying Minnesota law). "[I]n determining the adequacy of a warning, a court must consider 'the placement of the warning, its language and how it may or may not impress the average user.'" *Johnson v. Medtronic, Inc.*, 365 S.W.3d 226, 235 (Mo. Ct. App. 2012) (quoting *Brown v. Bay State Abrasives*, 821 S.W.2d 531, 533 (Mo. Ct. App. 1991)). "In evaluating these factors, the dangerous nature of the product, the form in which it is used, the burden to be imposed by requiring warnings and the likelihood that the particular warning will be adequately communicated to those who will foreseeably use the product must also be considered." *Id.* Here, Plaintiff makes several allegations as to Defendants' failure to warn. As such, the Court finds review of the adequacy of warnings is better served after a factual record has been established in this case. Nonetheless, the Court will address a few of Defendants' specific arguments here.

Defendants argue peripheral neuropathy is a known complication for those who use Zyvox for more than twenty-eight days, and Plaintiff even alleged this in her Complaint. This argument fails because the allegation in the Complaint does not establish when Plaintiff was aware of this, who knew of the complications with Zyvox, or whether any warnings were sufficient. It does not foreclose Plaintiff's failure to warn claim. Defendant also argues Plaintiff, in a previous lawsuit, alleged warnings were given to her medical providers as it related to Zyvox and peripheral neuropathy. This argument, while persuasive, goes to the adequacy of the warnings and fails for the reasons above.

Third, Defendant argues the learned intermediary doctrine warrants dismissal. "The learned intermediary doctrine is a corollary to the rule that a manufacturer of prescription drugs or products discharges its duty to warn by providing the physician with information about risks associated with those products." *Doe v. Alpha Therapeutic Corp.*, 3 S.W.3d 404, 419–20 (Mo. Ct.

[3] Defendants cite no other Missouri case for their argument that a charitable organization cannot be held strictly liable.

App. 1999). "The physician acts as a 'learned intermediary' between the manufacturer and the patient and any warning given to the physician is deemed a warning to the patient." *Id.* "If the doctor is properly warned of the possibility of a side effect in some patients, and is advised of the symptoms normally accompanying the side effect, there is an excellent chance that injury to the patient can be avoided." *Krug v. Sterling Drug, Inc.*, 416 S.W.2d 143, 151–52 (Mo. 1967). However, the learned intermediary doctrine is an affirmative defense and Plaintiff "was not required to plead facts tending to negate it in order to survive a motion to dismiss." *Redd v. DePuy Orthopaedics, Inc.*, 48 F. Supp. 3d 1261, 1271 (E.D. Mo. 2014). Therefore, Defendants' argument fails.

Finally, Defendants argue Plaintiff failed to plead proximate cause. This argument lacks merit as Plaintiff pleads she "used Zyvox . . . as a direct result of Defendants' approval and provision of a long term use of Zyvox, and their failure to adequately warn of the risks." (Doc. 1, ¶ 38.) Thus, Plaintiff has sufficiently pleaded proximate cause. Therefore, Defendants' arguments as to strict liability-failure to warn fail, and the motion to dismiss will be denied.

II. Plaintiff's Negligence Claims

In Missouri, in an action for negligence, the plaintiff must establish that "(1) the defendant had a duty to the plaintiff; (2) the defendant failed to perform that duty; and (3) the defendant's breach was the proximate cause of the plaintiff's injury." *See Martin v. City of Wash.*, 848 S.W.2d 487, 493 (Mo. 1993) (en banc). As in other common-law actions, the threshold matter in a negligence action is the existence of a duty. *Carman v. Wieland*, 406 S.W.3d 70, 76 (Mo. Ct. App. 2013). "The existence of a duty is unique among the elements of negligence because it is a question of law for the court to decide and hence this question is central to determining whether a party has a right to judgment as a matter of law." *Id*. (citation omitted); *see also Morrison v. Kubota Tractor Corp.*, 891 S.W.2d 422, 425 (Mo. Ct. App. 1994) ("In a negligence action, whether a duty exists is entirely a question of law for the court.")

Here, Defendants argue dismissal is warranted because no legal duty exists. As to the arguments regarding a duty to warn, these arguments fail for the reasons above. "Missouri courts have held that in cases involving manufacturers of prescription drugs, the manufacturer has 'a duty to properly warn the doctor of the dangers involved and it is incumbent upon the manufacturer to bring the warning home to the doctor.'" *Alpha Therapeutic Corp.*, 3 S.W.3d at 419 (Mo. Ct. App. 1999) (quoting *Krug*, 416 S.W.2d at 146).

As to the other allegations of negligence, Plaintiff cites no authority that additional duties exist for drug manufacturers under Missouri law. However, Plaintiff makes allegations and arguments to the effect that Defendants, through their actions, assumed a duty. *See Kraus v. Hy-Vee, Inc.*, 147 S.W.3d 907, 919–20 (Mo. Ct. App. 2004) ("If a defendant assumes a duty, by contract or by conduct, he can be held liable for injuries caused by the unsafe performance of that assumed duty.") (internal citations omitted). While the additional negligence claims asserted by Plaintiff may be foreclosed for lack of duty, the Court believes such determination is better suited at summary judgment. Therefore, Defendants' motion will be denied.

III. Plaintiff's Request for Punitive Damages

Defendants argue Plaintiff failed to sufficiently plead claims for punitive damages. Plaintiff, however, pleads Defendants acted intentionally, outrageously, willfully, and wantonly. She further pleads Defendants' conduct showed complete indifference and conscious disregard for the safety of others. While Plaintiff will have to substantiate these allegations with admissible evidence, the Complaint sufficiently pleads claims for punitive damages. Therefore, Defendants' motion will be denied.

Conclusion

Accordingly, and after careful consideration, Defendants' motion to dismiss (Doc. 14) is **DENIED**. Plaintiff's motion for leave to file a sur-reply (Doc. 38) and Defendants' motion to stay discovery. (Doc. 41) are **DENIED as MOOT**.

IT IS SO ORDERED.

s/ Roseann A. Ketchmark
ROSEANN A. KETCHMARK, JUDGE
UNITED STATES DISTRICT COURT

DATED: June 10, 2021